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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/925,778	08/09/2001	Deborah Dee Jaworski	GM50074	9516
20462	7590	10/07/2003	EXAMINER	
SMITHKLINE BEECHAM CORPORATION CORPORATE INTELLECTUAL PROPERTY-US, UW2220 P. O. BOX 1539 KING OF PRUSSIA, PA 19406-0939			WEBER, JON P	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 10/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/925,778

Applicant(s)

JAWORSKI ET AL.

Examiner

Jon P Weber, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 12-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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Status of the Claims

The response with amendments filed 11 August 2003 has been received and entered.

Claims 1-20 have been presented for examination.

Election/Restrictions

This application contains claims 12-20 drawn to an invention nonelected with traverse in the paper filed 19 February 2003. A complete reply to the final rejection **must** include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11 are now rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims now provide a negative limitation, "provided that said activity is not inhibition of DXR by fosmidomycin, fosfomycin, FR-33289 or FR-900098, or binding to DXR of fosmidomycin, fosfomycin, FR-33289 or FR-900098 to DXR." According to *In re Johnson*

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and Farnham, 194 USPQ 187, an applicant has the right to retreat to otherwise patentable species from a genus to which he erroneously thought he was entitled at filing. However, to be able to retreat to such species the applicant must be in possession of the genus. Further, there must be some basis for establishing the scope of the genus originally sought so that the species to which the applicant retreats are clearly enabled. It is the position of the Office that in the instant case, applicants were not in possession of the genus less the excluded species and that the negative limitations therefore constitute **new matter**. The basis for this position will be enlarged *infra*.

To be enabled for the instant genus, a compound that modulates an activity of a DXR reductoisomerase enzyme of *Haemophilus influenzae*, there must be an adequate written description of the genus. So the question is whether a person of ordinary skill in the art would know what compounds are within the scope of the claims given that a screening test is provided.

The breadth of the claims implies it is believed that 35 U.S.C. § 112, first paragraph permits an artisan to present claims of essentially limitless breadth so long as the specification provides one with the ability to test any particular embodiment which is encompassed by the material limitations of a claim and thereby distinguish between those embodiments which meet the functional limitations from those embodiments which don't. This argument is not entirely without merit. However, the issue here is the breadth of the claims in light of the predictability of the art as determined by the number of working examples, the skill level of the artisan and the guidance presented in the instant specification and the prior art of record. This 'make and test' position is inconsistent with the decisions of *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), *Amgen v. Chugai Pharmaceuticals Co. Ltd.*, 13 USPQ2d, 1737 (1990), and *In re Wands*,

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8 USPQ2d, 1400 (CAFC 1988). *In re Wands* stated that the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and, (8) the breadth of the claims.

The disclosure does not define a general let alone specific structural requirement for a modulator of DXR. A skilled artisan would not know where to start searching for such a compound given the guidance of the disclosure. The only working examples are those compounds explicitly excluded by the newly added limitations. In the art of enzymology, finding inhibitors for an enzyme is very challenging, even when the crystal structure is known. The art is replete with efforts to find inhibitors of target enzymes for therapeutic treatments. Usually inhibitors are found accidentally or because, as in this case, the enzyme target of an inhibitor is identified. Enormous resources are expended in an often, futile effort to find compounds that inhibit a specific target enzyme. These range from random high throughput screening efforts to molecular modeling/rational drug design when crystallographic information is available. Despite the tremendous effort, success is hard to come by. Even when inhibitors are found they are often unsuitable for therapeutic purposes for various reasons. Since the instant claims provide no limitation on the nature and structure of possible modulators of DXR the potential breadth of the claims is essentially unlimited. Given the total lack of additional non-excluded working examples, a skilled artisan would have to devote a major research endeavor to find other modulators of DXR.

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Breadth alone is not the issue, however. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), held that

"Inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some way on his teachings, since such improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; however, he must not be permitted to achieve this dominance by claims which are insufficiently supported and, hence, not in compliance with first paragraph of 35 U.S.C. 112; that paragraph requires that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved."

Having established the breadth of the claims, *Wands* now requires that one consider the number of working examples presented in the instant specification. It is noted that the only examples in the instant specification, working or prophetic, are the specific embodiments explicitly excluded by the negative limitation. Since there are **no** other working examples, then one must consider the guidance provided by the instant specification and the prior art of record. The instant specification provides absolutely no guidance as to which additional compounds are expected to modulate DXR. Further, there are no additional analogous compounds, which have been identified in the prior art for which this information is known and could be extrapolated to instant application by analogy. In conclusion, the instant claim encompasses a vast, almost limitless, number of modulator compounds and yet the instant specification provides no additional non-excluded working examples and no guidance that would permit an artisan to practice the invention commensurate with the scope of the instant claims.

The argument is based upon the premise that the standard under 35 U.S.C. § 112, first paragraph, is that of making and testing a compound modulate DXR to see if it obtains the

desired activity and properties. This is a position that has been routinely dismissed by the courts, as shown by those decisions cited above.

Further, *In re Wands* determined that the repetition of work which was disclosed in a patent application as producing a composition containing an antibody, which is a naturally occurring compound, did not constitute undue experimentation even if the antibody produced thereby was not identical to those that were disclosed in that application. The instant claims are not limited to any specific non-excluded compounds and the instant specification does not provide a description of a repeatable process of producing a modulator or DXR within the scope of the claims. To practice the instant invention in a manner consistent with the breadth of the claims would not require just a repetition of the work that is described in the instant application but a substantial inventive contribution on the part of a practitioner which would involve pulling compounds out of thin air which are required to modulate DXR. It is this additional characterization beyond disclosed modulators of DXR that is required in order to obtain the data needed to permit one to produce a non-excluded DXR modulator, which meets the requirements of the instant claims that constitutes undue experimentation.

These decisions have been relied upon in the instant rejection and by the court because they show that the judicial interpretation of the first paragraph of 35 U.S.C. § 112 requires that the breadth of claims must be based upon the predictability of the claimed subject matter and not on some standard of trial and error. To argue that one can make material embodiments of the invention and then test for those that work in the manner disclosed or that the instant claims only encompass the working embodiments is judicially unsound. Unless one has a **reasonable expectation** that any one material embodiment of the claimed invention would be more likely than not to function in the manner disclosed or the instant specification provides sufficient guidance to permit one to identify those embodiments which are **more likely to work that not** without actually making and testing them then the instant application does not support the

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breadth of the claims. In the instant case it is highly improbable that any compound will more likely than not perform in the manner disclosed and the instant specification does not provide the guidance needed to predictably obtain compounds with any reasonable expectation that the resulting compounds will function as a modulator of DXR.

This is a new matter rejection.

Claim Rejections - 35 USC § 103

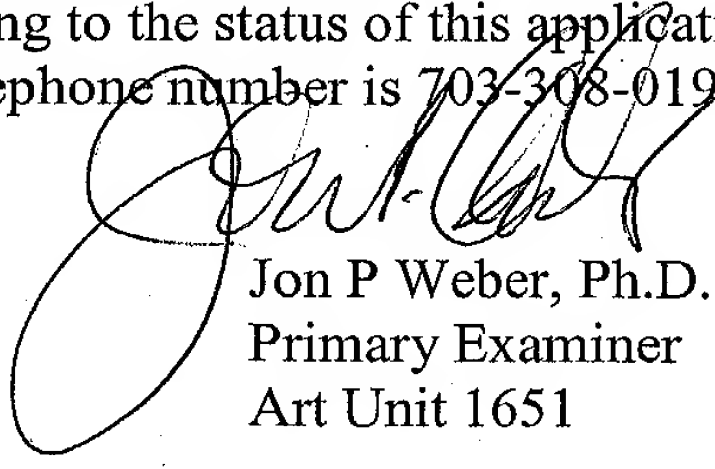
The rejection under this statute in the Office action of 07 May 2003 is withdrawn in view of the newly added negative limitations. However, withdrawal of these limitations in response to the new matter rejection *supra* would necessitate reinstatement of the art rejection.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon P Weber, Ph.D. whose telephone number is 703-308-4015. The examiner can normally be reached on daily, off 1st Fri, 9/5/4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 703-308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Jon P Weber, Ph.D.
Primary Examiner
Art Unit 1651

JPW
7 October 2003